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EXAMINER	
DEAK, LESLIE R	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,075	WIETING ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 June 2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-16 and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the amended claims, applicant claims that the filter assembly 8 comprises an impeller that does not substantially impart any linear forward or backward flow to the blood in the chamber. However, applicant does not disclose such a configuration in the specification. Applicant discloses that the instantly claimed filter assembly 8 may be deployed in a system as pictured in FIG 4

with a separate circulatory assist pump 68 that provides linear blood movement, but does not disclose that the impeller in filter assembly 8 provides no such linear movement. Furthermore, applicant discloses that in an embodiment, filter assembly 8 may serve as the primary pump in a cardiopulmonary bypass circuit (see paragraph 0049 of applicant's specification). Since applicant does not set forth any structural differences between the filter assembly 8 that is deployed merely as a gas separation chamber and the filter assembly that may act as the primary pump in the system, it follows that the filter assembly 8 necessarily imparts some linear motion to the blood within the chamber. Accordingly, Examiner can find no disclosure that supports the instantly claimed filter assembly.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 10, 12-14, 16, and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0110485 A1 to Stringer et al.

In the specification and figures, Stringer discloses the device as claimed by applicant. With regard to claim 1, Stringer discloses a blood handling system with gas removal comprising an axially elongate shell or housing 40 defining several chambers, including central void or chamber 51 (see FIG 3, paragraphs 0042-0044). The device

further comprises an impeller 75 that is connected to drive unit or motor 32, a gas vent 46 located at a central axis of the shell or housing, a blood inlet port 41, and a blood outlet port 42 located at the radial periphery of the shell or housing (see FIG 3).

Applicant claims that the impeller is "operable to" rotate a volume of blood within the shell, creating a centrifugal force within the blood, causing the air bubbles to act in a particular manner. Applicant's claim language requires only that the prior art is *capable* of operating as claimed (applicant's recitation that the impeller is "operable to" perform a function means only that it is able to, or capable of performing the claimed function). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). As such, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

Applicant further claims that the impeller does not substantially impart any force to drive blood in or out of the chamber. However, it is unclear to the examiner how an impeller that generates rotational force, moving fluid in a chamber with inlets and outlets on the side of the chamber, does not impart substantially any force to move fluid into or out of the chamber. Furthermore, applicant discloses that in an embodiment, filter assembly 8 may serve as the primary pump in a cardiopulmonary bypass circuit (see paragraph 0049 of applicant's specification). Since applicant does not set forth any structural differences between the filter assembly 8 that is deployed merely as a gas separation chamber and the filter assembly that may act as the primary pump in the

system, it follows that the filter assembly 8 necessarily imparts some linear motion to the blood within the chamber. Accordingly, it is the position of the examiner that the Stringer device meets the limitations of the claims.

With regard to claim 2, Stringer discloses that blood inlet 41 is located tangentially to the centerline of the housing or shell 40 (see paragraph 0046).

With regard to claim 3, Stringer discloses that the device comprises a baffled support structure 58 that is axially elongate, corresponding to applicant's claimed baffle (see FIG 3, paragraph 0048).

With regard to claims 4 and 5, applicant claims that the motor is electrically driven and that the motor and impeller are capable of rotating the impeller at a claimed RPM. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the motor disclosed by Stringer is capable of being electrically driven, and Stringer discloses that electrical lines may power the disclosed invention (see paragraph 0077). Furthermore, while Stringer is silent as to the rotational speed of the impeller, there is no disclosure indicating that the disclosed device may not operate as claimed by applicant, indicating that the Stringer impeller is capable of operating at the claimed RPM. Therefore, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 6, Stringer discloses that the gas vent 46 may be connected to a gas suction source 34, corresponding to applicant's claimed gas pump (see paragraph 0042).

With regard to claim 7, Stringer discloses a filter element 85 is disposed at the entrance to blood outlet manifold 47, which connects to blood outlet 42, meeting the limitations of the claims (see paragraph 0058).

With regard to claim 10, Stringer illustrates that blood inlet port 41 is located higher than blood outlet port 42 (see FIG 3).

With regard to claim 12, Stringer illustrates that gas outlet port 46 is located at the top of the housing 40, higher than the blood inlet port 41 and blood outlet port 42 (see FIG 3).

With regard to claims 13 and 14, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 and comprises a plurality of vanes 76 (see paragraph 0052).

With regard to claim 16, Stringer discloses that the gas removal port or vent 46 comprises a gas collection plenum 50 that collects or traps gas before venting, meeting the limitations of applicant's claim drawn to a gas trap (see paragraph 0046).

With regard to claim 24, Stringer discloses the shell, impeller, motor, vent, inlet, and outlet as claimed by applicant. Applicant further sets forth limitations drawn to the operation of the device. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does

not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that the impeller 75 is mounted on shaft 77 that is concentric with the axis of the shell, indicating that the impeller is capable of rotating as claimed by applicant, driven by motor or dive unit 32 (see paragraph 0052, 0061). Similarly, Stringer discloses that the device receives blood through inlet 41 from a patient via venous line 11 and delivers treated blood (including blood from which bubbles have been removed via gas removal system) to the patient through outlet 42 via arterial line 12 (see paragraph 0039, 0042). The Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). As such, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 25, With regard to claims 13 and 14, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 (see paragraph 0052). With regard to the manner of rotation, Stringer illustrates the impeller as contained entirely within shell or housing 40 (see FIG 3), indicating that the magnetic coupling

between the impeller 75 and drive unit 32 is capable of rotating the impeller through the housing or shell 40, meeting the limitations of the claim.

With regard to claims 26 and 27, Stringer discloses that the apparatus is intended to be part of an extracorporeal bypass system, indicating that the blood inlet port 41 and blood outlet port 42 are connected to blood handing system 30 (see FIG 1, paragraph 0038).

With regard to claims 28 and 29, applicant further sets forth limitations drawn to the operation of the device and the movement of blood therethrough. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). Furthermore, Stringer discloses that blood exits the device via blood outlet manifold 47 and blood outlet 41, located away from the gas collection plenum 50, minimizing gas/blood contact. Since Stringer suggests that the disclosed device is capable of operating as claimed by applicant, it meets the limitations of the claims.

With regard to claim 30, applicant claims a "means for adding," a "means for impelling," a "means for venting," and a "means for removing." The language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim

limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for " or "step for; "

(B) the "means for " or "step for " must be modified by functional language; and

(C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification. Applicant's specification provides reasonable support for the "means for" limitations above, indicating that the structure that performs the claimed functions comprise a blood inlet, an impeller, a gas vent, and a blood outlet.

Stringer specifically discloses a blood treatment device with a housing or shell 40, blood inlet 41, impeller 75, gas vent 46, and blood outlet 42, thereby meeting the structural limitations of the claim. With regard to applicant's recitation of the action of the impeller, the Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas

collection plenum, located at the center of the device (see paragraph 0059). As such, the Stringer device meets the limitations of the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 6,264,601 to Jassawalla et al.

In the specification and figures, Stringer discloses the device substantially as claimed by applicant (see rejection above) with the exception of the blood outlet extending tangentially from the housing or shell of the device.

Jassawalla discloses a ventricular assist device with a pumping portion that comprises an inlet and outlet to move blood through the treatment device. The inlet and outlet conduits 24, 26 and ports 54, 60, are both located tangentially from the cylindrical pumping chamber 20 (see column 7, lines 51-67). The tangential orientation of the ports 54, 60 are selected to most efficiently fill and evacuate the chambers of the pumping device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the blood outlet of the Stringer device in a tangential orientation to the housing as disclosed by Jassawalla in order to provide

efficient filling and evacuation of the chambers of the treatment device, as taught by Jassawalla (see column 7, lines 51-67).

5. Claims 9 and 15 are is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 6,769,871 to Yamazaki.

In the specification and figures, Stringer discloses the device substantially as claimed by applicant (see rejection above) with the exception of an antithrombogenic coating and a smooth impeller surface.

Yamazaki discloses a blood pump that circulates a patient's blood extracorporeally and prevents thrombus formation with an antihrombogenic coating made of a phospholipids bilayer and a small surface roughness. The coating is located on all surfaces that come into contact with the blood to reduce thrombus formation (see column 2, lines 5-30). The smooth impeller surfaces provide further thrombus suppression since blood will flow smoothly through the pump device (see column 3, lines 1-13). Therefore, it would have been obvious to one having ordinary skill in the art to provide the blood treatment and pumping device disclosed by Stringer with an antithrombogenic coating and smooth impeller surfaces as disclosed by Yamazaki, in order to prevent thrombus formation and allow long term deployment of the pump, as taught by Yamazaki (see column 2, lines 23-28).

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 5,823,987 to Elgas et al.

In the specification and figures, Stringer discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of placing the blood inlet

lower than the blood outlet. Elgas discloses an extracorporeal blood treatment device with a blood inlet 30 at the bottom of the device and a blood outlet 32 located above the inlet (see FIG 4). The position of the inlet and outlet provide a blood flow path that minimizes trauma to the blood cells and provides improved blood flow designed to minimize recirculation and stagnant areas (see column 2, lines 19-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to reverse the position of the blood inlet and outlet disclosed by Stringer in order to provide a blood path that minimizes recirculation and stagnant areas, as taught by Elgas (see column 2, lines 19-25).

7. In the alternative to the 35 USC 102 rejection presented above, claims 1-7, 10, 12-14, 16, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 4,919,802 to Katsura et al.

In the specification and figures, Stringer discloses the apparatus substantially as claimed (see rejection above) with the exception of the impeller imparting no substantial force to the inflow and outflow of blood through the chamber. Stringer discloses that the blood processing component 31 may be deployed in a standard extracorporeal circuit 10. Katsura discloses an extracorporeal blood filter that is deployed in an extracorporeal circuit with a pump 45 that imparts linear motion of the blood into and out of blood filter chamber 1. The components of the Katsura chamber impart no linear motion to the blood. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to omit the ability of the Stringer device to impart linear

motion to the blood in and out of the filter chamber, since it has been held that omission of a function of an element is obvious if the function of the element is not desired (see MPEP 2144.04(II)(A)), and allowing a secondary circulation pump as disclosed by Katsura to impart linear motion to the blood, as taught by Katsura.

With regard to claim 2, Stringer discloses that blood inlet 41 is located tangentially to the centerline of the housing or shell 40 (see paragraph 0046).

With regard to claim 3, Stringer discloses that the device comprises a baffled support structure 58 that is axially elongate, corresponding to applicant's claimed baffle (see FIG 3, paragraph 0048).

With regard to claims 4 and 5, applicant claims that the motor is electrically driven and that the motor and impeller are capable of rotating the impeller at a claimed RPM. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the motor disclosed by Stringer is capable of being electrically driven, and Stringer discloses that electrical lines may power the disclosed invention (see paragraph 0077). Furthermore, while Stringer is silent as to the rotational speed of the impeller, there is no disclosure indicating that the disclosed device may not operate as claimed by applicant, indicating that the Stringer impeller is capable of operating at the claimed RPM. Therefore, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 6, Stringer discloses that the gas vent 46 may be connected to a gas suction source 34, corresponding to applicant's claimed gas pump (see paragraph 0042).

With regard to claim 7, Stringer discloses a filter element 85 is disposed at the entrance to blood outlet manifold 47, which connects to blood outlet 42, meeting the limitations of the claims (see paragraph 0058).

With regard to claim 10, Stringer illustrates that blood inlet port 41 is located higher than blood outlet port 42 (see FIG 3).

With regard to claim 12, Stringer illustrates that gas outlet port 46 is located at the top of the housing 40, higher than the blood inlet port 41 and blood outlet port 42 (see FIG 3).

With regard to claims 13 and 14, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 and comprises a plurality of vanes 76 (see paragraph 0052).

With regard to claim 16, Stringer discloses that the gas removal port or vent 46 comprises a gas collection plenum 50 that collects or traps gas before venting, meeting the limitations of applicant's claim drawn to a gas trap (see paragraph 0046).

With regard to claim 24, Stringer discloses the shell, impeller, motor, vent, inlet, and outlet as claimed by applicant. Applicant further sets forth limitations drawn to the operation of the device. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does

not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that the impeller 75 is mounted on shaft 77 that is concentric with the axis of the shell, indicating that the impeller is capable of rotating as claimed by applicant, driven by motor or dive unit 32 (see paragraph 0052, 0061). Similarly, Stringer discloses that the device receives blood through inlet 41 from a patient via venous line 11 and delivers treated blood (including blood from which bubbles have been removed via gas removal system) to the patient through outlet 42 via arterial line 12 (see paragraph 0039, 0042). The Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). As such, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 25, With regard to claims 13 and 14, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 (see paragraph 0052). With regard to the manner of rotation, Stringer illustrates the impeller as contained entirely within shell or housing 40 (see FIG 3), indicating that the magnetic coupling

between the impeller 75 and drive unit 32 is capable of rotating the impeller through the housing or shell 40, meeting the limitations of the claim.

With regard to claims 26 and 27, Stringer discloses that the apparatus is intended to be part of an extracorporeal bypass system, indicating that the blood inlet port 41 and blood outlet port 42 are connected to blood handing system 30 (see FIG 1, paragraph 0038).

With regard to claims 28 and 29, applicant further sets forth limitations drawn to the operation of the device and the movement of blood therethrough. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). Furthermore, Stringer discloses that blood exits the device via blood outlet manifold 47 and blood outlet 41, located away from the gas collection plenum 50, minimizing gas/blood contact. Since Stringer suggests that the disclosed device is capable of operating as claimed by applicant, it meets the limitations of the claims.

With regard to claim 30, applicant claims a "means for adding," a "means for impelling," a "means for venting," and a "means for removing." The language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim

limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for " or "step for; "

(B) the "means for " or "step for " must be modified by functional language; and

(C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification. Applicant's specification provides reasonable support for the "means for" limitations above, indicating that the structure that performs the claimed functions comprise a blood inlet, an impeller, a gas vent, and a blood outlet.

Stringer specifically discloses a blood treatment device with a housing or shell 40, blood inlet 41, impeller 75, gas vent 46, and blood outlet 42, thereby meeting the structural limitations of the claim. With regard to applicant's recitation of the action of the impeller, the Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas

collection plenum, located at the center of the device (see paragraph 0059). As such, the Stringer device meets the limitations of the claim.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 4,919,802 to Katsura, further in view of US 6,264,601 to Jassawalla et al.

In the specification and figures, Stringer and Katsura disclose the device substantially as claimed by applicant (see rejection above) with the exception of the blood outlet extending tangentially from the housing or shell of the device.

Jassawalla discloses a ventricular assist device with a pumping portion that comprises an inlet and outlet to move blood through the treatment device. The inlet and outlet conduits 24, 26 and ports 54, 60, are both located tangentially from the cylindrical pumping chamber 20 (see column 7, lines 51-67). The tangential orientation of the ports 54, 60 are selected to most efficiently fill and evacuate the chambers of the pumping device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the blood outlet of the Stringer device in a tangential orientation to the housing as disclosed by Jassawalla in order to provide efficient filling and evacuation of the chambers of the treatment device, as taught by Jassawalla (see column 7, lines 51-67).

9. Claims 9 and 15 are is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 4,919,802 to Katsura, further in view of US 6,769,871 to Yamazaki.

In the specification and figures, Stringer and Katsura disclose the device substantially as claimed by applicant (see rejection above) with the exception of an antithrombogenic coating and a smooth impeller surface.

Yamazaki discloses a blood pump that circulates a patient's blood extracorporeally and prevents thrombus formation with an antihrombogenic coating made of a phospholipids bilayer and a small surface roughness. The coating is located on all surfaces that come into contact with the blood to reduce thrombus formation (see column 2, lines 5-30). The smooth impeller surfaces provide further thrombus suppression since blood will flow smoothly through the pump device (see column 3, lines 1-13). Therefore, it would have been obvious to one having ordinary skill in the art to provide the blood treatment and pumping device disclosed by Stringer with an antithrombogenic coating and smooth impeller surfaces as disclosed by Yamazaki, in order to prevent thrombus formation and allow long term deployment of the pump, as taught by Yamazaki (see column 2, lines 23-28).

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 4,919,802 to Katsura, further in view of US 5,823,987 to Elgas et al.

In the specification and figures, Stringer and Katsura disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of placing the blood inlet lower than the blood outlet. Elgas discloses an extracorporeal blood treatment device with a blood inlet 30 at the bottom of the device and a blood outlet 32 located above the inlet (see FIG 4). The position of the inlet and outlet provide a blood

flow path that minimizes trauma to the blood cells and provides improved blood flow designed to minimize recirculation and stagnant areas (see column 2, lines 19-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to reverse the position of the blood inlet and outlet disclosed by Stringer in order to provide a blood path that minimizes recirculation and stagnant areas, as taught by Elgas (see column 2, lines 19-25).

Response to Arguments

11. Applicant's amendment and arguments filed 21 June 2007 have been entered and fully considered but they are not persuasive.

12. Applicant argues that the impeller 75 of the Stringer device is not located in the same chamber of the gas collection plenum 50. However, impeller 75 is connected to plenum 50 by way of central void 50 and filter material 59, meeting applicant's limitations drawn to the placement of the impeller within the chamber of the axially elongate shell.

13. Applicant further argues that the impeller disclosed by Stringer is incapable of imparting centrifugal force to the blood circulating within the chamber. However, Stringer discloses that the pump of the disclosed is a centrifugal pump (indicating that it moves fluid via centrifugal motion) comprising an impeller 75 with a plurality of vanes 76 that rotate around shaft 77 to impart motion to the blood within the chamber. As a consequence of the construction of the chamber and the pump, Stringer discloses that blood swirls around or circulates around the central void, moved in part by impeller 75

(see paragraphs 0052, 0059, 0060). Accordingly, the impeller disclosed by Stringer is capable of, and does, in fact, impart rotational motion to the blood within the chamber, meeting the limitations of the claims. Applicant has not set forth any structural limitations that distinguish the instantly claimed invention from the Stringer device, rendering the device unpatentable over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit 3761
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